REMARKS

Upon entry of this paper, claims 1, 25, 26, 27 and 44 have been amended, no claims have been cancelled, and no claims have been added as new claims. Thus, claims 1-27 and 44-53 are presently pending in this application. No new matter has been added. The following comments address all stated grounds for rejection and place the presently pending claims, as identified above, in condition for allowance.

Applicants gratefully thank the examiner for the indication of allowability of claims 45-49. In addition, applicants respectfully submit that all claims pending in the present application are allowable as described herein.

Applicants further thank the examiner for the indication of allowability of claim 53, which corresponds to the subject matter of claim 3 re-written in independent form.

Claims 1, 25, 26, 27 and 44 are amended to clarify that the fluoropolymer material is *inelastic* in a radial or latitudinal direction (i.e., a direction that is perpendicular to the longitudinal direction). Support for the amendment can be found throughout the application as originally filed, at least, for example, on page 9, lines 21-28, page 10, lines 27-33 and page 18, lines 21-23.

Claims 1, 25, 26, 27 and 44 are also amended to modify the claim language to clarify that the member is deployable from a collapsed configuration to an expanded configuration, which is consistent with the original claim language and the specification. The modification of language from first and second diameters, to collapsed and expanded is merely a different way of stating the same action that has been thoroughly described and remarked upon by Applicants during the course of this prosecution. Accordingly, no new matter has been provided, and no new search is required.

Amendment of the claims is not to be construed as an acquiescence to any of the objections/rejections set forth in the instant Office Action, and was done solely to expedite

prosecution of the application. Applicant reserves the right to pursue the claims as originally filed, or similar claims, in this or one or more subsequent patent applications.

Claim Objections

Claim 3 was objected to as being dependent upon a rejected base claim. Applicants previously presented new claim 53, which incorporated the characteristics of claim 3 into the characteristics of claim 1, in strict compliance with the Examiner's suggestions.

In addition, Applicants consider claim 3 to be allowable, based on the remarks provided herein concerning the allowability of base claim 1.

Claim Rejections Under 35 U.S.C. §102

Claims 1, 2, 4-20, 24-27, 44, and 50-52 were rejected under 35 U.S.C. §102(e) as being anticipated by US Patent Number 5,269,755 to Bodicky, et al. (Bodicky '755). This anticipatory rejection is respectfully traversed in view of the following remarks.

According to the Examiner, the sheath 40 described in the Bodicky reference is capable of being stretched both longitudinally and radially, thus anticipating the claimed invention. In the Office Action issued March 11, 2004, in the Response to Arguments, it states, "Examiner asserts that since the sheath is made of ePTFE material, given sufficient fluid pressure, the sheath (40) also stretches in the radial direction (see column 5, lines 26-27 and lines 32-34)." In the Advisory Action, the Examiner asserts that certain references show ePTFE to be an elastic material.

Applicants respectfully disagree and maintain the language of Bodicky does not support the assertion that, "given sufficient fluid pressure, the sheath (40) also stretches in the radial direction." There is no disclosure in Bodicky '755 of an ePTFE sheath that is radially deployable from an expanded diameter to an even greater diameter with the addition of fluid pressure. Even if this action were disclosed in Bodicky '755, such a teaching fails to anticipate

the pending claims, which describe a collapsed configuration expanding to an expanded configuration.

Assuming, *arguendo*, that the sheath 40 of the Bodicky reference is capable of stretching in the radial direction, as alleged by the Examiner, such a teaching would preclude constructing the sheath 40 of Bodicky '755 from a radially or latitudinally *inelastic* material, as set forth in the claims. Rather, if the Examiner's assumption is correct, the sheath of Bodicky must be formed of an ***elastic*** material. For at least this reason, pending claims 1, 2, 4-20, 24-27, 44, and 50-52 distinguish patentably over the Bodicky reference.

In the present invention, the latitudinal direction is perpendicular to the longitudinal dimension, and the equivalent of a radial direction when the member is formed in a tubular structure. In the latitudinal direction (as applied in this discussion), the fluoropolymer material used to form the member is inelastic, as stated in Applicants' description ("The method includes the step of forming a tube of inelastic, fluoropolymer material" *see* Description, page 3). After the various processing steps performed to create the radially expandable device are completed as described, the fluoropolymer material is inelastic in the latitudinal/radial direction. The structure of nodes and fibrils creates a unique material that when formed into a tube or cylindrical type structure, will not stretch or change dimension in a perceptible manner in the radial/latitudinal/diametric dimension.

The Office Action of March 11, 2004 provides two sections of Bodicky '755 to support the assertion that the sheath of Bodicky is capable of being stretched in the longitudinal and radial direction. Lines 26-27 of Bodicky '755 state, "Pores E are formed between the interconnected nodes C and fibrils D. The size of the pores E is a function of whether fibrils D are stretched, relaxed or compressed between nodes C which is in turn a function of whether ePTFE sheath 40 is stretched or compressed. (underlined portion is specific to lines 26 and 27)" Lines 32-34 of Bodicky '755 state, " The chosen pore size of the pores E of the ePTFE material is a function of the viscosity of the medicament or other liquid as well as the injection pressure, if any, applied to the medicament or other liquid. (underlined portion is specific to lines 32-34)"

Applicants submit that this language in Bodicky specifically states the sheath can stretch or compress to adjust the pore size of the material. ***The stretching and compressing has no substantial effect on the diameter of the sheath***. The cited language, and Bodicky '755 in general, is describing a characteristic of ePTFE whereby *longitudinal stretching* of the material pulls fibrils taut, thereby increasing pore size, and *longitudinal compression* of the material creates "bent or wavy" fibrils (*see* Bodicky '755, col. 5, line 10) which decreases pore size. This description pertains to longitudinal stretching and compressing. ***This does not equate to expanding the diameter (radial) dimension of a tube or balloon formed of ePTFE***.

Accordingly, the disclosure of Bodicky '755 does not teach that the ePTFE is "deployable from a collapsed configuration to an expanded configuration." *See* amended claim 1. Nor does this language support the Examiner's assertion that "given sufficient fluid pressure, the sheath (40) also stretches".

However, if the language cited by the Examiner does indeed imply that the sheath of Bodicky *can* stretch in the radial direction, an assertion the Applicants respectfully traverse, the claims would still be patentable, because such a characteristic would preclude the sheath of Bodicky '755 from being formed of a radially *inelastic* material.

Applicants further maintain that the reference to the introduction of fluid pressure in Bodicky '755 has nothing to do with stretching the diameter of the sheath. Instead, the "injection pressure" is mentioned as one factor in determining what size to make the pores to result in the desired amount of liquid (having a certain viscosity) passing through the sheath.

The lines cited in the Office Action, as well as the Bodicky '755 reference in general, fail to disclose the use of fluid to expand the sheath "from a collapsed configuration to an expanded configuration." *See* amended claim 1. Applicants are requesting that the independent claims be amended to more clearly distinguish that the radially expandable device of the present invention starts in a collapsed configuration (as shown in **FIG. 1**) and upon the application of fluid pressure, expands to an expanded configuration (as shown in **FIG. 2**). Applicants would again like to stress that the radially expandable device of the present invention does not undergo substantial or perceptible stretching or expansion in the radial direction of the diameter of the

radially expandable device once the device is expanded. Instead, the radial expansion described and claimed refers to the initial configuration of a collapsed structure expanding to an expanded structure. This is a difference that is not disclosed, taught, or suggested in Bodicky '755.

As such, Applicants respectfully submit that Bodicky '755 fails to anticipate the pending claims. Applicants request reconsideration and withdrawal of this rejection.

Claim Rejections under 35 U.S.C. §103

Claims 21-23 and 51-52 were rejected under 35 U.S.C. §103 as allegedly being unpatentable over Bodicky '755. Applicants respectfully traverse this rejection in view of the following comments.

In view of the above remarks, Bodicky '755 fails to teach or suggest all elements of the pending claim 1, from which claims 21-23 depend. Claims 51-52 likewise depend from a claim (claim 50) that includes the same element in claim 1 of having a member deployable from a collapsed configuration to an expanded configuration (as amended). As such, Bodicky '755 fails to teach or suggest all elements of claim 50.

Applicants respectfully submit that unless a *prima facie* case of unpatentability with respect to known facts is established, applicants are not obliged to proffer any evidence of nonobviousness. To establish a *prima facie* case there must be some suggestion or motivation, either in the prior art or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine multiple reference teachings. There must then be a reasonable expectation of success. Finally, the prior art reference must teach or suggest all the claimed limitations.

Again, Applicants respectfully submit that the sheath 40 is not a radially expandable device as evidenced by the figures of Bodicky '755 and the detailed description, and if the sheath 40 of Bodicky '755 were radially expandable, the sheath 40 could not be formed of a radially inelastic material. The noted figures show the Foley catheter with the balloon portion on

the end of the catheter inflated. However, there is no indication in the figures of the sheath 40 experiencing any change in radial dimension. In fact, specific language as cited from columns 6 and 7 indicate that the seal prevents the sheath from existing in a collapsed configuration. The sheath cannot collapse, and due to the material properties of ePTFE, the sheath cannot substantially expand beyond the inflated state (when fluid pressure is provided) to stretch the diameter of the sheath. Thus, the sheath of Bodicky '755 is not a "radially expandable device."

Applicants, therefore, respectfully submit that the pending claims are non-obvious with respect to Bodicky '755. Reconsideration and withdrawal of this rejection are accordingly requested.

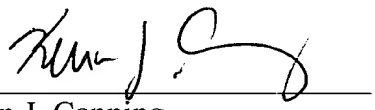
CONCLUSION

In view of the foregoing, it is respectfully submitted that this application is now in condition for allowance. Applicants courteously solicit allowance of the claims in the form of a Notice of Allowance. Should there be any outstanding issues of patentability following the entry of this response, a telephone interview is respectfully requested to resolve such issues.

Applicants believe no fee is due with this statement. However, if a fee is due, please charge our Deposit Account No. 12-0080, under Order No. ATA-257RCE from which the undersigned is authorized to draw.

Dated: September 10, 2004

Respectfully submitted,

By 

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